



**UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/494,149	01/28/00	MALECHA	S A-67641-1/RF

HM22/0727  
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EXAMINER	
PARAS JR, P	
ART UNIT	PAPER NUMBER
1632	6
DATE MAILED: 07/27/00	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

FIVE

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/494,149	MALECHA ET AL.	
	Examiner	Art Unit	
	Peter Paras, Jr.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 12-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

#### Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

**DETAILED ACTION**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to a composition comprising a shrimp or prawn androgenic polypeptide, a method of producing neomale shrimp or prawn using the same composition, and a population of shrimp or prawns produced by the same method, classified in class 424, subclass 198.1.
- II. Claim 12, drawn to a method of identifying an agent which binds to an androgenic polypeptide, classified in class 435, subclass 7.
- III. Claims 13-15, drawn to a method of identifying an agent which modulates the activity of an androgen, classified in class 435, subclass 4.
- IV. Claims 16-18, drawn to an antibody which binds an androgenic polypeptide, classified in class 530, subclass 387.1.
- V. Claim 16, drawn to an unknown agent which binds an androgenic polypeptide, is unclassifiable.

Inventions I and II-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The composition of

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group I can be used as a bio-affecting molecule to change the sex of shrimp or prawns. The methods and agents of groups II-V are drawn to agents which bind an androgenic polypeptide. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and requirement of a separate search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

During a telephone conversation with David Steck on 7/10/00 a provisional election was made without traverse to prosecute the invention of group I, claims 1-11. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 10-11 are directed to a population of shrimp or prawns having a skewed percentage of females to males, in particular when the percentage of females to males

is greater than about 90%. As such, the claims read on a product of nature which is non-statutory subject matter. Note, that claim 10 is a product by process claim in which the process carries little patentable weight because the product does not recite distinguishing features as a result of carrying out the claimed method. The claims are interpreted as being directed to a population of **normal** shrimp or prawns.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malecha et al (1992, Aquaculture, 105: 201-218) in view of Okuno et al (1997, Zoological Science, 14: 837-842) and Nagamine (1980, Gen. Comp. Endocrinol., 41: 442-457).

Claim 1 is directed to a composition comprising an isolated shrimp or prawn androgenic polypeptide. Claim 2 is directed to a neomale shrimp or prawn which does not contain transplanted androgenic gland tissue. Claim 3 is directed to a method of producing a neomale shrimp or prawn comprising treating a female shrimp or prawn with a composition containing an androgenic polypeptide. Claims 4-5 are directed to the same method whereing treating comprising injecting or contacting respectively.

Claim 6 is directed to a method of producing a population of shrimp or prawns having a skewed percentage of females to males comprising breeding a neomale shrimp or prawn which does not contain transplanted androgenic tissue with a wildtype female shrimp or prawn. Claims 7-9 are directed to the same method wherein the percentage of females is greater than 80% or 90%, or is 100% respectively.

Malecha et al teach a method of producing neomale prawns by implanting the androgenic gland into a female prawn. Malecha also teaches a method of cross-breeding neomale prawns with normal females to produce a population having a skewed percentage of females to males. Malecha also teaches that back-crossing progeny heterogametic females (XW) with a neomale will produce a skewed female population having a higher percentage of females to males (6.63: 1) [see table 6 page 212]. Malecha suggests that the sex of prawns is determined chromosomally (see page 215). Backcrosses between females and neomales (table 5), particularly neomale 7 crossed with female 3, resulted in absolute sex ratios of 1: 1518 and 0: 1809 [males to females] and suggested that if both neomale 7 and female 3 are homogametic (WW) all the resulting progeny would be female (page 215, paragraph 2).

Malecha et al differ from the claimed invention in that the neomales were produced by implanting androgenic tissue rather than by treating a female shrimp with a composition comprising an androgenic polypeptide.

However at the time the claimed invention was made, Okuno et al teach the purification of the androgenic gland hormone, from the terrestrial isopod *Armadillidium vulgare*, by reverse-phase high performance liquid chromatography (RP-HPLC).

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Masculinizing activity of the purified polypeptide was confirmed by injection into females (page 839 column 2). Furthermore, Nagamine teach a correlation between producing neomale prawns and shrimp as well as suggest a functional similarity between the androgenic glands and the androgenic hormone produced by these glands.

Specifically, Nagamine et al teach that similar results (of implantation of androgenic glands) have been observed in Amphipoda, Isopoda, and Decapoda (shrimp) and suggest that the androgenic glands (and the androgenic hormone produced by the androgenic glands) function similarly throughout these genres (see page 443, whole page, and abstract).

Accordingly in view of the teachings of Okuna and Nagamine, it would have been obvious for one of ordinary skill in the art to modify the teachings of Malecha by injecting an isolated androgen hormone polypeptide rather than implanting androgenic gland tissue into female shrimp or prawns to produce neomales and subsequently back-cross female progeny with a neomale to produce a population of shrimp or prawns with a skewed percentage of females to males. One of ordinary skill in the art would have been sufficiently motivated to inject an isolated androgen hormone polypeptide since such injection may reduce the number of experimental mortalities incurred by implantation of androgenic tissue as suggested by Malecha (page 213, see discussion paragraph 1).

### ***Conclusion***

**No claims are allowed.**

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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Stanton, can be reached at 703-308-2801. The FAX phone number for art unit 1632 is 703-308-0294.

Inquiries of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Peter Paras, Jr.

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*P. Paras, Jr.*  
*Patent Examiner*  
*1632*